

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Donald A. Schon, *et al.*

Confirmation No.: 9768

Application No.: 10/670,861

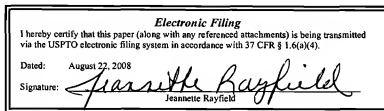
Group Art Unit: 3761

Filing Date: September 24, 2003

Examiner: Hand, Melanie Jo

For: Methods of Making a Multi-Lumen Catheter Assembly

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450



INFORMATION DISCLOSURE
STATEMENT

NOTICE OF PRIOR AND ONGOING LITIGATION INVOLVING RELATED PATENT

Further to notice provided in Applicants' Response and Amendment filed August 15, 2008, a Patent related to the present application, US 6,881,211 (the '211 Patent), is and has been involved in the following litigations:

(A) Medical Components, Inc. vs. Arrow International, Inc., Civil Action No. 07-2852 (E.D. Pa., filed July 11, 2007; and

(B) Medical Components, Inc. vs. Spire Biomedical, Inc., Civil Action No. 07-2853 (E.D. Pa., filed July 11, 2007; closed February 21, 2008.

The '211 Patent is a division of US 6,719,749 (the '749 Patent), the '749 Patent being a parent to the present application.

In compliance with MPEP § 2001.06(c), pleadings and discovery materials for the above-identified actions are enclosed herein. Those pleadings and discovery materials filed under seal, or

otherwise included under Protective Order, will be suitably submitted shortly in a Supplemental Information Disclosure Statement.

The '211 Patent owner, also Assignee of the present application, notes that the validity of the '211 Patent is currently being challenged by Arrow International, Inc., the Defendant in action A, above. Documents submitted herein include materials alleged by Arrow to invalidate the '211 Patent. For the convenience of the Examiner, the invalidity contentions and materials alleged by Arrow to invalidate the '211 Patent can primarily be found in attached citation nos. 5, 24, 37 and 38. These citation references are for convenience only, and are not intended to be strictly inclusive.

The '211 Patent owner further notes that the enforceability of the '211 Patent is currently being challenged by Defendant Arrow International, Inc., due to inequitable conduct. Inequitable conduct allegations are primarily included in, but not necessarily limited to, citation nos. 3 and 15. For the convenience of the Examiner, Applicant summarizes the pending inequitable conduct issues, as presented in citation no. 15, included as part of Arrow's Second Amended Counterclaims. Therein, Arrow alleges:

- a) in paragraphs 32-40, that Mr. Joseph Maenner, the attorney responsible for prosecuting the '749 patent, failed to include a complete written statement of the substance of an Examiner interview (occurring July 22, 2003) in a Response and Amendment to Office Action Mr. Maenner filed during prosecution of the '749 Patent, on August 6, 2003. Arrow alleges that the prosecution history of the '749 patent is therefore incomplete. In addition, in paragraph 40, Arrow alleges that there is no record of the catheter sample shown to the Examiner at the July 22, 2003, interview;
- b) in paragraphs 41-52, that Mr. Maenner breached his duty of candor in the method in which he submitted, by Information Disclosure Statement (IDS) during prosecution of the '749 Patent, Cook Inc., catheter catalog page(s). On August 23, 2003, Mr. Maenner received a letter from Cook, Inc., enclosing a copy of Cook catalog page(s) for their Uldall Double Lumen Hemodialysis Catheter. The cover letter stated that the Uldall Catheter was in public

use since 1993. Mr. Maenner disclosed the two Cook catalog page(s) as two separate references, and left the first page (or first reference) undated in the IDS. Further, Mr. Maenner did not include, in the IDS, the statement of Uldall Catheter public use since 1993. Mr. Maenner did submit US 5,106,368, issued April 21, 1992, for the Uldall Catheter;

- c) in paragraphs 53-57, that Dr. Schon, an inventor of the '749 Patent (and inventor in the present application), did not disclose the existence of the Uldall Double Lumen Hemodialysis Catheter to the Patent Office during prosecution of the '749 patent;
- d) in paragraphs 58-69, that, when the application for the '211 Patent was filed, Medical Components, Inc., already had the present application (the '861 application) on file, that claim 22 of the present application as-filed and claim 1 of the '211 Patent were "identical in all material aspects," and that Mr. Maenner breached his duty of disclosure for failing to disclose the existence of the present application in the pending application for the '211 Patent; and
- e) in paragraphs 70-80, that Mr. Bruce George, the attorney currently responsible for prosecuting the '861 application, did once amend claim 22 of the present application, making it "identical in all material aspects" to claim 1 of the '211 Patent, and has not told the Examiner of the present application of the existence of the '211 Patent.

In action B, above, now closed, Defendant Spire Biomedical, Inc., also brought challenges directed to the enforceability of the '211 Patent due to inequitable conduct. In citation no. 42, Spire alleged that, when the application for the '211 Patent was filed, Medical Components, Inc., already had the present application (the '861 application) on file, that claim 22 of the present application as-filed and claim 1 of the '211 Patent were "identical in all material aspects," that the applications were being pursued before two different examiners, and that the prosecuting attorney failed to tell either examiner about the existence of the other application. Action B settled, and Spire dismissed the above allegations of inequitable conduct with prejudice.

This IDS, and the Notice of Prior and Ongoing Litigation, should not be construed as an admission that the information cited is, or is considered to be, material to patentability as defined in 37

CFR § 1.56(b), and should not be construed as a representation that a search has been made or that the material has been reviewed for materiality.

In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in § 1.97(b), but before the mailing date of either a Final Action under § 1.116, or a Notice of Allowance under § 1.311, or before an action that otherwise closes prosecution in the application, therefore a fee in the amount of \$180.00 is enclosed under 37 CFR §1.17(p).

Please charge any additional fees for the papers being filed herewith and for which no check is enclosed, or credit any overpayment, to Deposit Account No. 02-2555.

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Respectfully submitted,

A handwritten signature in black ink, appearing to read "Bruce D. George", is written over a horizontal line.

Bruce D. George
Registration No. 43,631